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10/063,159	03/26/2002	Roger Akcrlund	6730.018.NPUS00	2733

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EXAMINER
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SHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

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12/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/063,159

Applicant(s)

AKERLUND ET AL.

Examiner

Laura C. Schell

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-26 and 28-49 is/are pending in the application.
- 4a) Of the above claim(s) 2, 4-7, 11, 14, 18, 22-25, 29 and 34-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 8, 10, 12, 13, 15-17, 19-21, 26, 28, 30-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Objections***

Claims 1 and 21 are objected to because of the following informalities: The examiner notes that claim 1 is labeled with the status identifier "currently amended", however, the amendment to claim 1 does not appear as being underlined. The examiner also notes that claim 21 is labeled with the status identifier "original", however Applicant's arguments state that claim 21 is amended to include the limitations of claim 27, however. Therefore the status identifier of claim 21 should be "currently amended" and the amendment to claim 21 should be underlined. The examiner brings this to the attention of Applicant for future reference. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 8, 10, 12, 16, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Scarrow (US Patent No. 5,061,264). Scarrow discloses a fluid transfer assembly (Fig. 1) for use in an infusion system, said assembly comprising: a fluid container (10) having an infusion fluid, a drug container (48) having a medical substance, at least one fluid barrier (74 and 14) controlling fluid passage between said

drug container and said fluid container, said fluid container further comprising at least one inlet port (12) for receiving said medical substance from said drug container, said drug container further comprising a cap (20) for sealing said drug container, said at least one inlet port further comprising a first luer lock connector (16; col. 3, line 14), and said cap further comprising a second luer lock connector (32; col. 3, lines 37-38 disclose that portion 32 is the connector that connects with luer lock connector 16) for attachment to said first luer lock connector, wherein said at least one fluid barrier is designed and arranged to be ruptured by an external force to allow said fluid passage (col. 3, line 27; col. 4, lines 41-42), wherein said drug container further comprises a neck (58) and said cap further comprises locking members (Fig. 10, members 140 and 141 work together to grasp the neck of the drug container) for grasping said neck (col. 2, lines 17-20 and col. 5, line 60 through col. 6, line 3 disclose that the assembly may be used without a housing (housing is element 50 in Fig. 1) and instead the cap may grasp only the drug container, also see Fig. 10).

In reference to claim 3, Scarrow discloses that the cap further comprises a protruding member (28) forming a second fluid duct between said drug container and said second luer lock connector, wherein said fluid barrier is provided inside said second fluid duct (rupturable barrier 74 is within 28, as 28 extends all the way into the cap portion to where 74 is located).

In reference to claim 8, Scarrow discloses that the second luer lock connector further comprises a pierceable closure (72) for protection before use.

In reference to claim 10, Scarrow discloses that the drug container further comprises an opening sealed by a closure (60), and said cap further comprising a hollow needle (70) for penetrating said closure.

In reference to claim 12, Scarrow discloses that the drug container further comprises a neck (58), said cap further comprising a protruding member (28) forming a second fluid duct between said drug container and said second luer-lock connector, and said cap further comprising locking members (fig. 10 discloses locking members 140 and 141 work together to grasp the neck; also see col. 5, line 60 through col. 6, line 3) for grasping said neck.

In reference to claim 16, Scarrow discloses that the fluid container further comprises a protruding resilient tube (12 protrudes externally from the inside of the fluid container), said first luer lock connector (16) of said at least one inlet port being provided on a hollow spike member (spike part of 14) able to be firmly retained inside said tube.

In reference to claim 19, Scarrow discloses that the cap further comprises a protruding member (28) forming a second fluid duct between said drug container and said second luer lock connector, said fluid barrier being provided inside said second fluid duct (rupturable barrier 74 is within 28, as 28 extends all the way into the cap portion to where 74 is located), said drug container comprising a rigid material (col. 3, line 65), said protruding member comprising a more flexible material than said second luer connector and said drug container, and said fluid barrier comprising a more brittle

material than said drug container, said protruding portion, and said second luer lock connector (col. 4, lines 41-42).

In reference to claim 20, Scarrow discloses that the composition of said drug container is selected from the group consisting of glass and a rigid polymer material (col. 3, line 65 discloses the drug container is glass).

Claims 21, 26, 28, 30, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Scarrow (US Patent No. 5,061,264). Scarrow discloses a drug container (48) comprising: a fixed dose of a medical substance, and a cap (20) for sealing said drug container, said cap further comprising a luer lock connector (32; col. 3, lines 37-38 disclose that portion 32 is the connector that connects with luer lock connector 16) for attachment to a corresponding connector (16) provided on an inlet port (12) of a container for infusion fluid (10), thereby creating a luer lock coupling, said drug container further comprising a neck (58), and said cap further comprising locking members (Fig. 10, members 140 and 141 work together to grasp the neck of the drug container) for grasping said neck (col. 2, lines 17-20 and col. 5, line 60 through col. 6, line 3 disclose that the assembly may be used without a housing (housing is element 50 in Fig. 1) and instead the cap may grasp only the drug container, also see Fig. 10).

In reference to claim 26, Scarrow discloses a pierceable closure (72) for protecting said second luer lock connector (72 is perfectly capable of protecting the luer lock connector (32) from anything that may enter from the open end of 46).

In reference to claim 28, Scarrow discloses that the drug container further comprise an opening sealed by a closure (60), and said cap further comprises a hollow needle (70) for penetrating said closure.

In reference to claim 30, Scarrow discloses that the drug container further comprises a neck (58), said cap further comprises a protruding member (28) forming a second fluid duct between said drug container and said second luer lock connector, and said cap further comprising locking members (locking members 140 and 141 work together to grasp the neck of the drug container; also see col. 5, line 60 through col. 6, line 3) for grasping said neck.

In reference to claim 32, Scarrow discloses that the cap further comprises a protruding member (28) forming a fluid duct between said drug container and said luer lock connector, wherein a fluid barrier is provided inside said fluid duct (rupturable barrier 74 is within 28, as 28 extends all the way into the cap portion to where 74 is located), said drug container comprising a rigid material (col. 3, line 65 discloses the drug container is glass), said protruding member comprising a more flexible material than said luer lock connector and said drug container, and said fluid barrier is made of a more brittle material than said drug container (col. 4, lines 41-42)., said protruding portion, and said luer lock connector.

### ***Response to Arguments***

Applicant's arguments filed 2/27/2007 have been fully considered but they are not persuasive. Applicant argues that Scarrow does not disclose the claim limitation of the drug container comprising a neck and the cap further comprising locking members for grasping said neck. However, as presented above, when reading through the Scarrow reference and looking at Fig. 10, the Scarrow reference does indeed disclose the possibility of directly coupling the drug container (48) to the cap by using the locking members on the cap without using a housing surrounding the drug container (locking members are elements 140 and 141 in Fig. 10) to lock onto the neck of the drug container (col. 2, lines 17-20 and col. 5, line 60 through col. 6, line 3). Therefore the Scarrow reference still anticipates the claims.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LCS

*LCS*

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

